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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,303	12/02/2005	Colin Dunlop	GRIHAC P44AUS	3549
20210 7590 01/31/2011 DAVIS & BUJOLD, P.L.L.C. 112 PLEASANT STREET CONCORD, NH 03301				
EXAMINER				
HELLING, KAITLYN ELIZABETH				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,303

Applicant(s)

DUNLOP, COLIN

Examiner

KAITLYN E. HELLING

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16, 18, 19, 21-27, 29, 30, 32 and 34-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16, 18, 19, 21-27, 29, 30, 32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 10 September 2010 has been entered. Claims 1-4, 17, 2028 and 38 are cancelled. Claims 15, 16, 18, 19, 21-27, 29, 30, 32 and 34-38 are currently pending.

Response to Arguments

2. Applicant's argument that modifying the convective hypothermia article of Berke '400 as proposed to include the porous material, as disclosed by Irani '370 would render the convective article of Berke '400 unsatisfactory for its intended purpose and that the combination would change the principle of operation of the convective article is not found to be persuasive. Applicant provides the reasoning that the convective hypothermia article of Berke '400 operates by directing "jets" of warm air and points to the Berke '400 specification as Col. 3, lines 63-65. However, in review of this section of the Berke '400 specification, the examiner has not found there to be support for applicants assertion that the convective hypothermia article of Berke '400 operates by directing "jets" of warmed air. This section of the Berke '400 specification simply states the placement of the porous portion can be either designed for maximum or optimum air flow. This does not explicitly or implicitly mean that the device operates by directing "jets" of warmed air. Therefore, as the intended purpose of the Berke '400 reference and that of the Irani '370 reference are both to warm a subject and the mode through which this is accomplished is through convection using porous materials and air flow through those materials the examiner maintains the combination of Berke '400 and Irani '370.

3. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

4. Regarding applicant's argument that even if a person of ordinary skill in the art were to consider the disclosure of the three document together, that person would appreciate that the heat transfer layer of Irani '370 would not be suitable for use with the type of articles as disclosed by Berke '400 and Tomic-Edgar et al. '144, the examiner respectfully disagrees. Applicant claims that because the heat transfer layer of Irani '370 captures or retains heat from the air chamber, it would not be capable of providing a sufficient volume of air to be defused. The examiner would point out that Irani '370 teaches that the heat transfer layer "captures or retains heat from the air chamber and then diffusively circulates the same." The materials of Berke '400 and Tomic-Edgar et al. '144 are going to perform in a similar manner as the space between the orifices or holes are going to capture or retain heat while the air diffuses through the orifices or holes. There will be some retention of heat within any material. Stated another way the heat transfer layer takes the heat from the air chamber and circulates that heat. The mechanism of circulation of the heat is still the air.

5. The examiner does not agree with applicant's conclusive statement that it is highly unlikely that the patient would be warmed at all significantly provided with the combination of references as the heat transfer layer of Irani '370 is not capable of delivering a sufficient volume of air. How did applicant arrive at this conclusion? There is no supporting evidence that this is true. Also, applicant does not require or claim a specific volume of air that is considered to be sufficient.

6. The bulk of applicant's arguments seem to rely on the fact that Irani '370 covers the subject but Berke '400 and Tomic-Edgar et al. '144 surround the subject. The examiner does not find this to be persuasive as the purpose and mode of operation are the same for all of the reference.

Claim Rejections - 35 USC § 112

7. Claims 27, 32, 34-36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 27 recites "the small animal" and then "a small animal." Are these meant to be the same small animal? The examiner is unsure as to what applicant means by a small animal having a relatively large surface area to volume ratio. Do all small animals have this property? Additionally, small is a relative term and is not defined by the claim or the specification.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 15-16, 18-19, 21 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke (US 5165400) in view of Tomic-Edgar et al (US 6277144 B1) and Irani (US 5405370).

Berke discloses a surgical warming blanket (10) comprising at least two layers (see Fig 5) capable of forming hollow air space between the two layers (hollow legs 13 and 14, Fig 1) for receiving warmed air from a heating unit (11), the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space (see Fig 1), whereby when warm air is passes into the air space the warm air is delivered to the patient receiving space via the blanket (column 2 lines 34-40), to maintain warm air within the patient receiving space, the patient receiving space being arranged to receive the patient's body and allowing access to the patient's body for surgery without disturbing the blanket (as is clearly shown in Fig 1). Berke does not specifically disclose that one of the two layers of the blanket has a portion of its surface formed of porous material so that the air is delivered to the patient receiving space via the entire surface of the porous material. Berke also does not disclose a blanket base for the patient to lie on.

Tomic-Edgar et al teaches an inflatable patient warming apparatus similar to the Berke apparatus (see Fig 1A), wherein there is an external surface layer (400) constructed of any soft material suited for contact with a patient's body (column 6 lines 52-59). With the configuration taught by Tomic-Edgar, the warmed air is delivered to the patient receiving space via the entire surface of the porous material. Tomic-Edgar also teaches a continuation of one of the layers provides a blanket base within the patient

receiving space, arranged for the patient to lie on (column 4 lines 8-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Berke by including an external surface layer as taught by Tomic-Edgar in order to provide a soft material to contact a patient's skin, and by adding the blanket base, as taught by Tomic-Edgar in order to add structural stability to the apparatus.

However, neither Berke nor Tomic-Edgar teaches that the warmed air is delivered to the patient receiving space by diffusing over the entire surface of the porous material at a relatively low velocity so as to have the effect of evenly warming the patient without forming relatively high velocity streams of air. Irani teaches an air blanket (10) arrangement that comprises a barrier layer (14) that is substantially impervious to airflow and a heat transfer layer (18) that are joined together to form a chamber adapted for the reception of warm air (abstract) where the air from the chamber penetrates and uniformly diffuses through the heat transfer layer to gently impinge upon the treated patient (abstract and Col. 3, line 56-Col. 5, line 19). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the porous material of Irani with the materials of Berke and Tomic-Edgar as Irani teaches that using such a material allows for the gentle impinging of the heated air substantially over the entire surface of the blanket (Col. 3, lines 56-63).

Regarding claims 16, 18-19, 21 and 30, Berke in view of Tomic-Edgar and Irani discloses the surgical warming blanket described above, with Berke and the further limitations of wherein the tubular arrangement surrounds the patient receiving space on three sides (see Figs 1 and 2), wherein the surface of the blanket is arranged to be fluid

repellent (column 3 line 33-34), and wherein the surgical warming blanket is sized and shaped so that the patient receiving space is arranged to receive a human (see Fig 1) and is also capable of receiving an animal (such as a large dog or a monkey), and a small animal (small being a relative term and including a monkey or small cow) whereby to maintain warmth of the human or animal.

Regarding claim 29, Berke in view of Tomic-Edgar and Irani discloses a method of warming a patient comprising the steps of receiving the patient within a patient receiving space within which the patient's body is accessible for surgery, and passing warmed air into a patient receiving space to keep the patient warm utilizing the surgical warming blanket as described above (see the abstract, column 1 lines 15-24 and column 2 lines 10-11).

11. Claims 22-26 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke in view of Tomic-Edgar, Irani and Hagopian (US 4963997).

Regarding claims 22-26, Berke in view of Tomic-Edgar and Irani discloses patient warming system as described above, with Berke further teaching a heating unit (11) including a delivery port (opening 16, Fig 3) for delivering warmed air to the patient warming blanket, described above, and a safety monitoring means for automatic shut-off (column 3 lines 6-8); the heating unit being arranged to heat the air to a range of temperatures, including up to 46 degrees C (column 3 lines 3- 6). Berke does not disclose a pressure sensor feedback system. Hagopian teaches an inflatable patient support system (Fig 1) with a control unit (10), pumps (22 and 24) and ports (88 and 90) for delivering air to the device and a feedback means for determining whether a patient

warming blanket is attached; wherein the feedback means includes a pressure sensor for sensing back pressure on the air delivery port (column 4 line 65- column 5 line 17). Furthermore, pressure feedback systems are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Berke by adding the pressure sensor feedback system as taught by Hagopian to the automatic shut-off safety mechanism in order to appropriately inflate the patient warming blanket to desired values when the blanket is attached.

Regarding claim 37, Berke discloses a surgical warming blanket (10) comprising at least two layers (see Fig 5) capable of forming hollow air space between the two layers (hollow legs 13 and 14, Fig 1) for receiving warmed air from a heating unit (11), the two layers and air space being arranged in operation to form a substantially tubular arrangement at least partially surrounding a patient receiving space (see Fig 1), whereby when warm air is passes into the air space the warm air is delivered to the patient receiving space via the blanket (column 2 lines 34-40), to maintain warm air within the patient receiving space, the patient receiving space being arranged to receive the patient's body and allowing access to the patient's body for surgery without disturbing the blanket (as is clearly shown in Fig 1), a heating unit including a delivery port (opening 16, Fig 3) for delivering warmed air to the patient warming blanket, described above, and a safety monitoring means for automatic shut-off (column 3 lines 6-8), and the heating unit being arranged to heat the air to a range of temperatures, including up to 46 degrees C (column 3 lines 3- 6). Berke does not specifically disclose that a first layer of the two layers of the blanket is formed of porous material so that the

air is delivered to the patient receiving space via the entirety of the first layer, a blanket base for the patient to lie on, or a pressure sensor feedback system.

Tomic-Edgar et al teaches an inflatable patient warming apparatus similar to the Berke apparatus (see Fig 1A), wherein there is an external surface layer (400) constructed of any soft material suited for contact with a patient's body (column 6 lines 52-59). With the configuration taught by Tomic-Edgar, the warmed air is delivered to the patient receiving space via the entire surface of the porous material. Tomic-Edgar also teaches a continuation of one of the layers provides a blanket base within the patient receiving space, arranged for the patient to lie on (column 4 lines 8-19). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Berke by including an external surface layer as taught by Tomic-Edgar in order to provide a soft material to contact a patient's skin, and by adding the blanket base, as taught by Tomic-Edgar in order to add structural stability to the apparatus.

However, neither Berke nor Tomic-Edgar teaches that the porous material has substantially uniform porosity and wherein warmed air is delivered to the patient receiving space by diffusing over the entirety of the first layer at a relatively low velocity so as to have the effect of evenly warming the patient without forming relatively high velocity streams of air. Irani teaches an air blanket (10) arrangement that comprises a barrier layer (14) that is substantially impervious to airflow and a heat transfer layer (18) that are joined together to form a chamber adapted for the reception of warm air (abstract) where the air from the chamber penetrates and uniformly diffuses through the heat transfer layer (which inherently has a substantially uniform porosity as the entire

heat transfer layer is made from the same material) to gently impinge upon the treated patient (abstract and Col. 3, line 56-Col. 5, line 19). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the porous material of Irani with the materials of Berke and Tomic-Edgar as Irani teaches that using such a material allows for the gentle impinging of the heated air substantially over the entire surface of the blanket (Col. 3, lines 56-63).

Hagopian teaches an inflatable patient support system (Fig 1) with a control unit (10), pumps (22 and 24) and ports (88 and 90) for delivering air to the device and a feedback means for determining whether a patient warming blanket is attached; wherein the feedback means includes a pressure sensor for sensing back pressure on the air delivery port (column 4 line 65- column 5 line 17). Furthermore, pressure feedback systems are well known in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Berke, Tomic-Edgar and Irani by adding the pressure sensor feedback system as taught by Hagopian to the automatic shut-off safety mechanism in order to appropriately inflate the patient warming blanket to desired values when the blanket is attached.

12. Claims 27, 32, 34-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke (US 5165400) in view of Tomic-Edgar et al (US 6277144 B1), Irani (US 5405370) and US 6,440,157 B1 to Shigezawa et al. (Shigezawa).

Regarding claims 27, 29 and 32-36, Berke in view of Tomic-Edgar and Irani discloses a method of warming a patient comprising the steps of receiving the patient within a patient receiving space within which the patient's body is accessible for surgery,

and passing warmed air into a patient receiving space to keep the patient warm utilizing the surgical warming blanket as described above (see rejections of previous claims and see the abstract, column 1 lines 15-24 and column 2 lines 10-11). However, neither Berke, Tomic-Edgar nor Irani specifically teach that the warm air is being supplied at a temperature of about 46 degrees C. Shigezawa teaches an air warming system for providing a controlled temperature air to an air blanket (title) as well as that typically the air temperature ranges from ambient temperature to 48 degrees Celsius. Therefore, as Berke, Tomic-Edgar, Irani and Shigezawa teach heater units that are programmable to a desired temperature and it is known that to treat hypothermia typically high temperatures are required, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the method to include supplying the air at the temperature of Shigezawa in order to keep a patient warm as desired. This is especially true in light of applicant's lack of any criticality for the claimed temperature.

Regarding claim 38, the above references don't state specific dimensions of the warming blanket. However, it would have been obvious to one having ordinary skill in the art to dimension the warming blanket as necessary as where the only difference between the prior art and the claimed device is a recitation of relative dimensions and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device is not patentably distinct from the prior art device. This is especially true in light of the lack of any disclosed criticality for the claimed dimensions.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,674,269 to Augustine teaches a patient warming system with user-configurable access panel (title) comprising an elongate member, inflatable and formable into an enclosure that surrounds a patient and defines a thermal care zone and a plurality of exhaust ports open through sides of the inflatable member to exhaust the thermally-controlled medium (See Figs. 1, 4 and abstract) where depending upon the size of the inflatable member it may be used to treat anyone from a small child to an adult (Col. 7, lines 38-51).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAITLYN E. HELLING whose telephone number is (571)270-5845. The examiner can normally be reached on Monday - Friday 9:00 a.m. to 5:30 p.m. EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KAITLYN E. HELLING/
Examiner, Art Unit 3739

/Linda C Dvorak/
Supervisory Patent Examiner, Art
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